

DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 27 October 2010 in which claims 1-57, 59, 61, 64-67, 70-74 and 77 were cancelled, and claims 58, 62, 63, 68, 69, 75, 78 and 79 are amended to change the scope and breadth of the claims.

Claims 58, 60, 62, 63, 68, 69, 75, 76, 78 and 79 are pending in the instant application and are examined on its merits herein.

Priority

This application claims priority to U.S. provisional application no. 60/456,208 filed on 20 March 2003.

Rejections Withdrawn

Applicants' remarks, filed 27 October 2010, with respect to the rejection of claims 75-79 under 35 USC § 112, first paragraph, for lacking written description support in U.S. provisional application no. 60/456,208, has been fully considered and is persuasive. Applicants have identified that support for the claimed concentration of 0.3 mg/mL in DMSO can be found in Tables 1 and 2 of U.S. provisional application no. 60/456,208. This rejection has been **withdrawn**. Thus, the claims are accorded the priority date of 20 March 2003, as indicated above.

Applicants' amendment and remarks, filed 27 October 2010, with respect to the rejection of claims 58-63, 68 and 69 under 35 USC § 102(b), as being anticipated by

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journal publication by Bisht *et al.*, have been fully considered and are persuasive. The rejection is being withdrawn because the applied prior art is only applicable to the method of preparing the sophorolipid, as recited in steps (a)-(d) of independent claim 58, and Bisht *et al.* do not teach a method of using their sophorolipid in the manner claimed in step (e), as recited in the instant claim limitations. This rejection has been **withdrawn**.

Applicants' amendment and remarks, filed 27 October 2010, with respect to the rejection of claims 75-79 under 35 USC § 103(a), as being unpatentable over journal publication by Bisht *et al.*, in view of U.S. Patent No. 5,981,497 to Maingault, in view of publication by Kandil *et al.*, in view of chapter publication by Wilkinson *et al.*, in view of chapter publication by Chattaraj *et al.*, have been fully considered and are persuasive. The rejection is being withdrawn because the applied prior art is only applicable to the method of preparing the sophorolipid, as recited in steps (a)-(d) of independent claim 75, and the combined teachings of the prior art do not teach a method of using their sophorolipid in the manner claimed in step (e), as recited in the instant claim limitations. This rejection has been **withdrawn**.

In view of the cancellation of claims 1-57, 59, 61, 64-67, 70-74 and 77, all rejections made with respect to claims 1-57, 59, 61, 64-67, 70-74 and 77 in the previous Office Action are withdrawn.

Applicants are requested to note that the originally filed claims, dated 19 March 2004, were subject to a three-way restriction requirement dated 10 April 2007 that

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included (i) a sophorolipid compound and a composition thereof, (ii) a process for preparing a sophorolipid compound, and (iii) a method for inactivating spermatozoa or viruses using the sophorolipid compound. Thus, Applicants' amendment to the claims to further include a method of using the sophorolipid composition is an improper amendment as it attempts to include non-elected subject matter into the elected claimed subject matter. As discussed in the Restriction Requirement of record, the method of using the sophorolipid is directed to an invention that is independent or distinct from the invention originally claimed drawn to a method for preparation of the sophorolipid. Thus, while the rejections of record have been withdrawn because the applied art is not applicable to Applicants' instant amendments, no further prior art rejections are being applied as the further step for a method of using the sophorolipid is drawn to non-elected subject matter.

The following are new grounds of rejections necessitated by Applicants' amendment, filed on 27 October 2010, wherein the limitations in pending claims 58 and 75 as amended now have been changed; claims 60, 62, 63, 68 and 69 depend from claim 58, and claims 76, 78 and 79 depend from claim 75.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 60, 62, 63, 68, 69, 75, 76, 78 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation “method for preparing and using a dispensable sophorolipid compound” in claims 58 and 75 is noted as a “hybrid” claim as the claims are drawn to multiple categories of inventions, e.g. drawn to a process of making and a process of using. These claims are ambiguous because the recited method steps do not necessarily result in the claimed composition. Specifically, steps (a)-(d) of claims 58 and 75 are drawn to methods for the preparation of a dispensable sophorolipid compound. However, step (e) then takes the dispensable sophorolipid compound and uses it to treat sperms or viruses for spermicidal or virucidal purposes. It is not known whether the sophorolipid compound remains unchanged or whether it is metabolized to exert its spermicidal or virucidal properties. Furthermore, even if Applicants were to argue that the sophorolipid compound remains unchanged when used for spermicidal or virucidal purposes, the composition treated with sperms or viruses is no longer useful for additional treatment of sperms or viruses. Moreover, upon treatment of sperms or viruses, the formulation no longer exists and it is unclear how the sophorolipid could be dispensed. In order to overcome the ambiguity of the claimed methods, it is respectfully recommended that Applicants re-write the claims into separate categories, e.g., specific claims drawn to a method of preparation and specific claims drawn to a method of using. However, Applicants are requested to note that when written separately, the claims are subject to the restriction requirements of record, as discussed above.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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